

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference -----	FOR FURTHER ACTION See Form PCT/PEA416	
International application No. PCT/EP2004/052492	International filing date (day/month/year) 11.10.2004	Priority date (day/month/year) 13.10.2003
International Patent Classification (IPC) or national classification and IPC C12N1/20, C12R1/01		
Applicant GESELLSCHAFT FÜR BIOTECHNOLOGISCHE FORSCHUNG et al		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input checked="" type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 01.12.2005	Date of completion of this report 19.01.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Bassias, I Telephone No. +49 89 2399-8106 	

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International application No.
PCT/EP2004/052492

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-16 as originally filed

Sequence listings part of the description, Pages

1-31 as originally filed

Claims, Numbers

1-10 received on 01.12.2005 with letter of 01.12.2005

Drawings, Sheets

1/15-15/15 as originally filed

Drawings, Figures

1-10 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. II Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
- ☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
 - ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:
see separate sheet

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-10
	No: Claims	-
Inventive step (IS)	Yes: Claims	1-6
	No: Claims	7-10
Industrial applicability (IA)	Yes: Claims	1-10
	No: Claims	-

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

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Re Items II/VI

1. It appears that the priority is validly claimed. Consequently, the documents cited in the International Search Report as "P/X"-documents are not considered prior art.

Re Item V

1. The present application relates to processes for producing a protein by heterologous expression in a host microorganism which contains the gene sequence for the heterologous protein and the DNA sequence encoding the chaperonins Cpn60 and/or Cpn10 (SEQ ID NOs: 1 and/or 2) from the psychrophilic bacterium *Oleispira antarctica*. Furthermore, plants are claimed which are able to grow at lower temperatures due to the presence of a DNA sequence encoding a cold active functional chaperonin (in particular Cpn60 and/or Cpn10).
2. The amended claims filed with the letter of 01.12.2005 appear to be allowable under Articles 19(2) and 34(2)(b) PCT.
3. Reference is made to the following document:

D1: DATABASE EMBL [Online] 13 August 2002 (2002-08-13), "*Oleispira antarctica* cpn10 gene for cochaperonin 10 and cpn60 gene for chaperonin 60" XP002337742 retrieved from EBI accession no. EM_PRO:OAN505131 Database accession no. OAN505131
4. The genes encoding cpn10 and cpn 60 from *Oleispira antarctica* are known from the prior art (D1). However, a process as described in claim 1 with a host microorganism containing the specific genes encoding cpn10 and/or cpn 60 (SEQ ID NOs: 1 and/or 2) to be used for producing heterologous proteins is not known in the prior art. Furthermore, there are no indications that the use of said genes for protein expression would have any beneficial effect, in particular if the host cells are grown at low temperatures.
Consequently, it appears that the subject-matter of claims 1-6 meets the

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requirements of Article 33(2) and (3) PCT.

5. Claim 7 refers to a plant which is able to grow at lower ambient temperatures due to the presence of genes encoding cold active functional chaperonins. Claim 8 is limited to such a plant comprising the specific genes encoding cpn10 and/or cpn 60 from *Oleispira antarctica*.

Plants comprising heterologous genes for cold active chaperonins were never produced. Although a person skilled in the art would know how to introduce heterologous genes in plants, one cannot consider that the requirements of Article 5 and 6 PCT are met. A bacterial chaperonin may function in a heterologous bacterium but it cannot be automatically assumed that this function, which would enable the plant to grow at lower temperatures, will be also present in a plant.

In view of this lacking experimental demonstration of these kind of plants with such cold adaptations no technical problem is solved convincingly and thus no inventive activity can be acknowledged for claims 7-9 (Article 33(3) PCT).

6. Since no such plant exists, the use of such a non-existing plant (claim 10) contravenes also the requirements of Article 33(3) PCT.